DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 4, 2014

Biomet Spine
Ms. Kimberly McCoy
Regulatory Affairs Project Manager
310 Interlocken Parkway, Suite 120
Broomfield, Colorado 80021

Re: K140710
Trade/Device Name: Biomet Graft Delivery Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: July 22, 2014
Received: July 24, 2014

Dear Ms. McCoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140710

Device Name
Biomet Graft Delivery Syringe

Indications for Use *(Describe)*
The Biomet Graft Delivery Syringes are intended to deliver autograft, allograft or synthetic bone grafting materials to all orthopedic surgical sites.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date:	July 22, 2014
Applicant/Sponsor:	Biomet Spine 310 Interlocken Parkway, Suite 120 Broomfield, CO 80021
Contact Person:	Kimberly McCoy MBA, RAC Regulatory Affairs Project Manager Phone: 303.465.8923 Fax: 303.501.8444
Trade name:	Biomet Graft Delivery Syringes
Common Name:	Piston Syringe for grafting material
Device Class:	Class II
Classification Name: (Product Code):	Piston Syringe (FMF)
Device Panel - Regulation No.:	General Hospital - 21 CFR 880.5860

Device Description:

The Biomet Graft Delivery Syringes provide the surgeon with a method to manually deliver bone grafting material such as allograft, autograft and synthetic bone grafting materials to all orthopedic surgical sites. The sterile syringes are available in three different sizes to hold different volumes of grafting materials. The graft delivery syringe consist of a syringe barrel with a plunger, a removable female luer cap and removable end cap and will be provided empty or pre-filled with commercially available bone grafting materials. The syringes will be available with and without an internal stainless steel strainer.

Indications for Use:

The Biomet Graft Delivery Syringes are intended to deliver autograft, allograft or synthetic bone grafting materials to all orthopedic surgical sites.

Substantial Equivalence:

The Biomet Graft Delivery System is substantially equivalent to the CDO™ and Graft Preparation Systems (K072330), the Arthrex Mixing and Delivery System (K121124), the InFill™ Graft Delivery System (K121476 & K111632) and Biomet's Graft Delivery System (K021071). The technological characteristics of the subject Biomet Graft Delivery System is the same as, or similar to, the predicate devices in regards to intended use, indications for use, design, materials, fundamental technology, and operational principles.

Performance Data:

Simulated use testing was conducted to demonstrate the device functions as intended to deliver bone graft materials to an orthopedic surgical site. The testing verifies that the subject device is

substantially equivalent to other graft delivery systems currently on the market for its intended use and does not raise any new issues regarding safety and effectiveness.

Conclusion:

The Biomet Graft Delivery System is substantially equivalent to the predicate syringes as a graft delivery syringe in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles. Furthermore, testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject devices to the named predicate systems, which have been cleared for delivering graft material to orthopedic surgical sites. Based on this information, the subject devices do not raise any new issues regarding the safety or efficacy when compared to its predicates.